Information for Healthcare Professionals
Fentanyl Transdermal System (marketed as Duragesic and generics)

FDA ALERT 7/15/2005; Update 12/21/2007: This update highlights important information on appropriate prescribing, dose selection, and the safe use of the fentanyl transdermal system.

In July 2005, FDA issued a *Public Health Advisory* and *Information for Healthcare Professionals* that emphasized the appropriate and safe use of the fentanyl transdermal system (fentanyl patch), marketed as Duragesic and generics). Despite these efforts FDA has continued to receive reports of death and life-threatening adverse events related to fentanyl overdose that have occurred when the fentanyl patch was used to treat pain in opioid-naïve patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source.

The fentanyl patch is only indicated for use in patients with persistent, moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are considered to be opioid-tolerant. Patients must avoid exposing the patch to excessive heat as this promotes the release of fentanyl from the patch and increases the absorption of fentanyl through the skin which can result in fatal overdose. The directions for prescribing and using the fentanyl patch must be followed exactly to prevent death or other serious side effects from fentanyl overdose. These directions are provided in the current *prescribing information* and *Instructions for Applying a Fentanyl Transdermal Patch* and the new *Medication Guide* for patients
http://www.fda.gov/cder/foi/label/2005/19813s039lbl.pdf

This information reflects FDA's current analysis of data available concerning this drug. FDA intends to update this when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program and complete a form on line at http://www.fda.gov/medwatch/report/hcp.htm or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.

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the fentanyl patch. Healthcare professionals who prescribe the fentanyl transdermal system (fentanyl patch) should be fully aware of all the prescribing information and should instruct patients on the proper use of the fentanyl patch. The FDA and manufacturer are revising the current labeling to highlight the following safety information in the prescribing information and Instructions for Applying a Fentanyl Transdermal Patch and a new Medication Guide for patients.

Recommendations and Considerations for Healthcare Professionals

- **The fentanyl patch is indicated for the management of persistent, moderate to severe chronic pain in opioid-tolerant patients 2 years of age or older who require a total daily opioid dose at least equivalent to fentanyl transdermal system 25 mcg/h.** Opioid-tolerant patients are those who have been taking daily, for a week or longer, at least 60 mg of morphine, 30 mg of oral oxycodone, or at least 8 mg of oral hydromorphone or an equianalgesic dose of another opioid. Fentanyl patch use in non-opioid tolerant patients has resulted in fatal respiratory depression.

- **Consult the prescribing information to determine the initial fentanyl patch dose. Overestimating the dose when converting patients from another opioid analgesic can result in fatal overdose with the first dose.**

- **The fentanyl patch is contraindicated in the management of post-operative pain, mild pain, or intermittent pain (e.g. use on an as needed basis) because of the risk for serious or life-threatening respiratory depression. Fatalities from fentanyl overdose have occurred in these situations.**

- **Concomitant use of the fentanyl patch with any cytochrome P450 3A4 inhibitors (such as ketoconazole, erythromycin, nefazodone, diltiazem, or grapefruit juice) may result in an increase in fentanyl plasma concentrations, which may cause potentially fatal respiratory depression.** Carefully monitor patients concomitantly taking cytochrome P450 3A4 inhibitors and using the patch for an extended period of time and adjust the fentanyl dose if necessary.

Information for the patient: *Physicians who are prescribing the fentanyl patch should ensure that their patients and their caregivers understand the following:*

- **The fentanyl patch contains fentanyl, a very strong opioid narcotic medicine that can cause life-threatening breathing problems and death if it is not used correctly.** Use the patch exactly as prescribed by your doctor.

- **Only use the fentanyl patch if you have been regularly taking other strong narcotic pain medicines for at least a week.** If this is not your situation, talk to your doctor about other options for managing your pain. The patch must not be used to treat mild pain or pain following surgery, medical or dental procedures.

- **Tell your doctor about all the medicines you take.** Some medicines may interact with the fentanyl released from the patch and result in dangerously high levels of fentanyl in your blood that could lead to serious and life-threatening breathing problems.

- **Life-threatening breathing problems can happen because of an overdose. Call your doctor right away or get emergency medical help if you have:**

  - trouble breathing or slow or shallow breathing
  - slow heartbeat
  - severe sleepiness
  - cold, clammy skin
  - trouble walking or talking or feeling faint, dizzy, or confused

- **Read and understand the instructions for applying the fentanyl patch that you receive with your prescription.** Apply the patch to intact skin. If it falls off before 72 hours, fold the sticky side together and flush down a toilet. Put a new one on at a different skin site. Be sure to let your doctor know that this has happened.

- **Heat may increase the amount of fentanyl that reaches your blood and can cause life-threatening breathing problems which can lead to death.**
  - Do not use heat sources such as heating pads, electric blankets, saunas, or heated waterbeds while wearing a fentanyl skin patch.
  - Do not take hot baths or sun bathe while wearing a patch.
  - Call your doctor right away if you get a fever higher than 102ºF.

Background Information and Data

On July 15, 2005 FDA issued a *Public Health Advisory* and *Information for Healthcare Professionals* that described reports of death and other serious adverse events related to narcotic overdose in patients using fentanyl patches for pain control. At that time, the prescribing information was updated to add new safety information and the manufacturer of Duragesic, Janssen Pharmaceutical Products, issued a "Dear Healthcare Professional" letter that described the changes to the prescribing information.

Despite these efforts, FDA has continued to receive reports that indicate physicians are still inappropriately prescribing and patients are continuing to incorrectly use fentanyl patches. The reports indicate that physicians have prescribed the patch to treat acute or intermittent pain in opioid-naïve patients. Also, reports reveal that patients have applied more fentanyl patches than prescribed, changed patches too frequently, and/or exposed patches to a heat source. In some situations, patients have experienced severe respiratory depression and some have died due to fentanyl overdose.

At the request of FDA, the manufacturers of fentanyl transdermal systems are revising the prescribing information, and patient instructions for use and are developing a new Medication Guide for patients.

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Date created: December 21, 2007

FDA/Center for Drug Evaluation and Research